

REMARKS

In the Action, claims 1, 4-7, 10, 11 and 13-16 are rejected. In response, new claims 17-19 are added. Thus, the pending claims in this application are claims 1, 4-7, 10, 11 and 13-19, with claims 1 and 17 being independent.

New claim 17 is added to recite a mechanically compressed compact consisting essentially of a lactic acid menthyl ester component which comprises at least 95 wt% lactic acid menthyl ester and where the compact is in the absence of inorganic salts and is stable for an extended period of time. Claim 17 is supported by the specification and claims as originally filed. New claims 18 and 19 depend from claim 17 and recite the compact comprising 98 wt% of the lactic acid menthyl ester and 99 wt% of the lactic acid menthyl ester, respectively.

In view of these amendments and the following comments, reconsideration and allowance are requested.

Obviousness-Type Double Patenting Rejection

Claims 1, 4-7, 10, 11 and 13-16 are provisionally rejected for obviousness-type double patenting over the claims of copending application Serial No. 10/516,005 in view of U.S. Patent Publication No. 2003/0235545 to Guenin et al. The copending application is cited for disclosing a compact of alpha-menthol where the compact comprises at least 90 wt% alpha-menthol. Guenin et al. is cited for disclosing a composition comprising menthyl lactate. The rejection is based on the premise that it would have been obvious to substitute the alpha-menthol of the copending application with the menthyl lactate of Guenin et al.

As noted in the Action, the claims of the copending application are specifically directed to a compact of alpha-menthol and not lactic acid menthyl ester. Alpha-menthol is a specific crystal structure of menthol having specific properties such as the melting point that are not possessed by other forms of menthol or menthyl lactate. Furthermore, Guenin et al. specifically

discloses a soft solid cosmetic composition comprising 0.01 to 0.5 wt% of a cooling agent such as l-menthol, menthyl lactate, menthone, glycerine, menthone glycerin acetal, or other components. The composition of Guenin et al. comprises 40 to 75 wt% of a volatile silicone and up to 20 wt% of a non-emulsifying silicone elastomer. Thus, the resulting composition contains no more than 0.5 wt% of the cooling agent.

The use of the small amount of a cooling agent in Guenin et al. provides no suggestion to one of ordinary skill in the art to replace the alpha-menthol with another cooling agent. Furthermore, Guenin et al. discloses menthyl lactate as one of nine possible cooling agents. There is no basis for randomly selecting one of the cooling agents that is used in an amount of up to 0.5 wt% and forming a compact containing at least 95 wt% of menthyl lactate as in the claimed invention. Accordingly, Applicant submits that the claims of the present application are not obvious over the copending application either alone or in combination with Guenin et al.

In view of the above comments, Applicant requests the provisional obviousness-type double patenting rejection be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 1, 6 and 13-16 are rejected under 35 U.S.C. § 103 as being obvious over WO 95/07683 to Eis et al. in view of U.S. Patent No. 7,201,922 to Serpelloni. Eis et al. is cited for disclosing a composition for oral or topical administration that can include a coolant such as menthyl lactate. Serpelloni is cited for disclosing a process of forming tablets. The rejection is based on the position that it would have been obvious to form a compressed tablet from a randomly selected single component of Eis et al. using the compression force disclosed in Serpelloni.

Eis et al. and Serpelloni either standing alone or in combination do not disclose or suggest a compact comprising at least 95 wt% lactic acid menthyl ester as recited in claim 1.

The cited patents provide no suggestion of forming a compact of a menthyl ester. As noted in the Action, Eis et al. discloses a composition comprising at least 75 wt% of a carrier. As disclosed on page 7 of Eis et al., the composition comprises 75 to 99.999% by weight of a carrier. Eis et al. does not disclose or suggest the carrier being menthol as suggested in the Action. Furthermore, Eis et al. clearly does not disclose a composition comprising 75 to 99 wt% menthol as suggested in the Action. Thus, the statement on page 5 of the Action indicating that Eis et al. discloses the claimed coolant in the claimed amount is clearly incorrect.

Furthermore, Eis et al. provides no suggestion of using menthol or menthyl lactate in its natural form. The passages referred to in the Action refer to menthol and menthyl as a reactant to produce one or more phosphate derivatives. As specifically disclosed on page 3, lines 15-24, the phosphate compounds are formulated by phosphorylating a coolant, sweetener, or flavorant component. Thus, the menthol referred to in Eis et al. is a reactant that is phosphorylated to form the desired phosphate derivative. Accordingly, Eis et al. provides no suggestion of forming a compact from menthol or menthyl lactate as asserted in the Action. Moreover, page 6, lines 11-13 specifically disclose the phosphate derivatives being present in an amount of 0.001 to 25 wt% of the total composition. Thus, the amount of the menthol phosphate derivative is well below the claimed range.

Serpelloni is relevant only to the extent that a table or pellet is formed. The resulting tablet of Serpelloni includes granules of lactose and starch. This has no relation to the claimed invention or the composition of Eis et al. Accordingly, the combination of Eis et al. and Serpelloni provide no suggestion of forming a mechanically compressed lactic acid menthyl ester where the compact comprises at least 95 wt% lactic acid menthyl ester. Accordingly, claim 1 is not obvious over Eis et al. and Serpelloni. Claims 6 and 13-16 are also not obvious for reciting additional features of the invention that are not disclosed or suggested in the combination of the cited patents.

Claims 1, 6 and 13-16 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,397,573 to Kajs et al. in view of Eis et al. and Serpelloni. Kajs et al. is cited for disclosing a laxative composition comprising 1% to 99% menthol. The rejection is based on the position that it would have been obvious to replace the menthol of Kajs et al. with the coolants disclosed in Eis et al.

Kajs et al., Eis et al. and Serpelloni either standing alone or in combination provide no suggestion of forming a mechanically compressed compact containing at least 95 wt% lactic acid menthyl ester as recited in claim 1. As noted in the Action, Kajs et al. is directed to a laxative composition comprising menthol. Kajs et al. does not disclose that menthyl lactate is an equivalent for use in the laxative composition. Furthermore, the Action provides no basis for the position that it would have been obvious to replace the menthol of Kajs et al. with the menthyl lactate for a laxative composition. Moreover, Kajs et al. does not suggest a compact comprising at least 95 wt% of menthol or lactic acid menthyl ester. Kajs et al. discloses menthol which is typically in the form of peppermint oil. Thus, the actual menthol content of Kajs et al. in the final composition is not disclosed.

As disclosed on page 1 of the specification, lactic acid menthyl ester is typically available in the form of a solidified distillate which develops an acidic, pungent odor over a period of several weeks which causes the lactic acid menthyl ester to be unusable for the majority of the intended applications. The invention is specifically directed to the discovery that lactic acid menthyl ester can be compressed to form a compact comprising at least 95 wt% lactic acid menthyl ester that are stable for an extended period of time compared to the commercially available forms of lactic acid menthyl ester. The mechanically compressed lactic acid menthyl ester of the invention does not exhibit a change in acid number during storage as disclosed on page 2 of the specification. Kajs et al. does not disclose or suggest producing a stable form of lactic acid menthyl ester as in the claimed invention. Furthermore, one skilled in the art would

not have been motivated to replace the menthol of Kajs et al. with the lactic acid menthyl ester as in the present invention. Kajs et al. is specifically directed to a laxative composition where the menthol is released in the lower gastrointestinal tract. Kajs et al. is not concerned with forming a compact or mechanically compressed composition containing at least 95 wt% lactic acid menthyl ester.

As noted above, Eis et al. does not disclose the use of lactic acid menthyl ester in a composition or that lactic acid menthyl ester is an equivalent of menthol. The menthol or other cooling agent of Eis et al. is used as an intermediate for producing the phosphate derivative. It would not have been obvious to one of ordinary skill in the art to randomly select a particular reactant for producing a phosphate derivative as disclosed in Eis et al. to replace the menthol of Kajs et al. Serpelloni is relevant only to the extent that a compressed tablet is disclosed. Accordingly, it would not have been obvious to produce a mechanically compressed composition containing at least 95 wt% lactic acid menthyl ester in view of Kajs et al., Eis et al. and Serpelloni. Thus, claims 1 and dependent claims 6 and 13-16 are allowable over the combination of the cited patents.

Claims 4, 5, 7, 10 and 11 are rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Eis et al. in view of Serpelloni and U.S. Patent No. 5,783,725 to Kuhn et al. These claims are also rejected as being obvious over the combination of Kajs et al. in view of Eis et al. and Serpelloni and Kuhn et al.

For the reasons discussed above, Eis et al. does not disclose or suggest a mechanically compressed menthol or lactic acid menthyl ester as in the claimed invention. Eis et al. refers to a composition containing a phosphate derivative and a carrier material where the carrier is present in an amount of at least 75 wt%. Furthermore, Eis et al. only discloses the menthol or coolant component as a reactant. As disclosed on page 3, the phosphate derivatives are formed by phosphorylating at least one coolant, sweetener or flavorant component. See also the formula on

page 2 which refers to the R group of the phosphate derivative as being a coolant component, sweetener component and a flavor component. Thus, the coolant disclosed in Eis et al. is used only in the form of a phosphate derivative. This provides no suggestion to one of ordinary skill in the art to use the coolants in an amount of at least 95 wt% as recited in claim 1.

Kuhn et al. is cited for disclosing lactic acid menthyl ester in a stabilized form by the addition of an alkali metal carbonate and/or bicarbonate and/or alkaline earth metal carbonate and/or bicarbonate. Kuhn et al. provides no suggestion of a mechanically compressed lactic acid menthyl ester to form a compact comprising at least 95 wt% lactic acid menthyl ester. The method and composition of Kuhn et al. form a solution of the lactic acid menthyl ester in acetone with sodium bicarbonate. The solution is allowed to cool to form crystals of the lactic acid menthyl ester. There is no suggestion of a mechanically compressed lactic acid menthyl ester as claimed.

Moreover, Kuhn et al. also discloses that lactic acid menthyl ester is generally unstable and produces a pungent smell which renders it unusable for most intended uses. See, for example, column 1, lines 37-40. Kuhn et al. is specifically directed to crystallizing the lactic acid menthyl ester in the presence of a carbonate or bicarbonate salt to form shelf stable crystals. Kuhn et al. provides no indication that lactic acid menthyl ester can be mechanically compressed to form a stable composition as in the claimed invention.

The Action incorrectly asserts that Eis et al. discloses the claimed coolant in a compressed dosage form. Eis et al. only discloses a composition containing at phosphate derivative of a coolant in an amount well below the claimed range. Kuhn et al. provides no suggestion of replacing the phosphate derivative of Eis et al. with the crystallized lactic acid menthyl ester. Even if one were to do so, the resulting composition would not be the claimed mechanically compressed compact containing at least 95 wt% lactic acid menthyl ester as recited in the claims.

Kajs et al. further fails to disclose or suggest a mechanically compressed compact of lactic acid menthyl ester. Eis et al. and Kuhn et al. provide no suggestion of replacing the menthol of Kajs et al. with a lactic acid menthyl ester. The art of record as a whole provides no suggestion that the lactic acid menthyl ester would function as the laxative composition in Kajs et al. Therefore, one skilled in the art would not have been motivated to replace the menthol of Kajs et al. with the lactic acid menthyl ester to form a mechanically compressed compact as in the claimed invention.

In view of the deficiencies of the cited patents, the claims are allowable over the combination of the cited patents. For example, the cited patents provide no suggestion of using L-lactic acid L-menthyl ester as in claim 4, the compaction force of flaked lactic acid menthyl ester as in claim 5, the flaked lactic acid menthyl ester having a purity of at least 95% as in claim 7, the L-lactic acid L-menthyl ester of claim 10, or the compression force of claim 11 either standing alone or in combination with the independent claims.

Independent claim 17 is also allowable over the art of record for reciting a mechanically compressed compact consisting essentially of lactic acid menthyl ester. The cited patents further fail to disclose the lactic acid menthyl ester component comprising at least 95 wt% lactic acid menthyl ester and where the compact is in the absence of inorganic salts to produce a compact that is stable for an extended period of time. The art of record clearly fails to disclose a stable compact of lactic acid menthyl ester. Claims 18 and 19 are allowable as depending from claim 17 and for reciting the compact comprising 98 wt% and 99 wt% lactic acid menthyl ester, respectively.

In view of the above comments, the claims are submitted as being allowable over the art of record. Accordingly, reconsideration and allowance are requested.

Respectfully submitted,



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